

the opinion that the use of tartaric acid in cigarettes is not generally recognized among experts qualified to evaluate the safety of drugs, as safe for use in a recurring condition such as obesity. Assuming that Dr. Smith, a Government employee, told claimant's attorney that it would be unnecessary for claimant to file a new drug application with the Administration, claimant's failure to comply with the statute in that regard cannot be excused under the theory of estoppel against the Government. See *Wilber National Bank v. United States*, 1935, 294 U.S. 120.

"For the reasons expressed in the foregoing opinion, I conclude that libelant's motion for summary judgment should prevail. An appropriate order may be presented accordingly."

On 12-21-59, an order was entered in accordance with the above opinion granting summary judgment in favor of the Government and ordering that the article be condemned and destroyed.

**6305. Trim Reducing-Aid cigarettes.** (F.D.C. No. 42220. S. No. 23-656P.)

**QUANTITY:** 47 shipping cases, each containing 30 bulk ctns., of which each contained 1 display ctn. containing 10 retail packages, at Glendale, Calif.

**SHIPPED:** 9-9-58, by Cornell Drug Corp., New York, N.Y.

**LABEL IN PART:** (Pkg.) "TRIM Reducing-Aid Cigarettes Filter Tip—20 Active ingredients: Combustible tartaric acid, combined with tobacco and flavoring. Directions for use: Smoke one cigarette shortly before meals . . . and whenever you are tempted to reach for a late evening snack \* \* \* contain a patented appetite satient that takes the edge off your appetite \* \* \* Cornell Drug Corp."; (display ctn.) "NEW TRIM Reducing-Aid Cigarettes \* \* \* Smoke 3 or 4 a day CURBS YOUR APPETITE \* \* \* Clinically tested, Satisfaction guaranteed. A scientific blend of finest quality tobaccos U.S.A. Patent No. 2,773,785 \* \* \* Not intended to replace your favorite cigarette—nor to change your present smoking habits."

**ACCOMPANYING LABELING:** Pamphlets entitled "Mr. Retailer How to Get Your Share of a \* \* \* \$500,000,000 Market."

**LIBELED:** 10-15-58, S. Dist. Calif.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that smoking three *Trim cigarettes* per day would bring about a definite weight loss over a given period of time; that *Trim cigarettes* were safe for use by all persons; that use of *Trim cigarettes* enabled one to lose weight without dieting; that the user of *Trim cigarettes* could continue to eat the same kinds and amounts of food he ordinarily consumed and still lose weight; that *Trim cigarettes* were a new, scientific discovery approved by doctors and other scientists; that *Trim cigarettes* were marketed only after being subjected to years of clinical tests by doctors and other scientists; and that *Trim cigarettes* were the miracle reducing discovery of the century; 502(b)(1)—the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

**DISPOSITION:** Cornell Drug Corp., filed a claim and answer to the libel. Thereafter, various motions were made and proceedings occurred as set forth below in the following findings of fact, conclusions of law, and summary judgment entered by the court on 1-11-60:

MATHEY, *District Judge*:

FINDINGS OF FACT

"1. On or about September 9, 1958, Cornell Drug Corporation shipped the following items from New York, New York, to Glenway Company, 4427 San Fernando Road, Glendale, California:

a. 47 shipping cases, more or less, each containing 30 bulk cartons each of which contains 1 display carton containing 10 retail packages of an article labeled in part 'TRIM Reducing-Aid Cigarettes' and

b. 500 pamphlets, more or less, identified in part by the statements 'Mr. Retailer How to Get Your Share of a . . . \$500,000,000 Market.'

"2. On October 15, 1958, the United States of America, libelant herein, filed a Libel of Information against said articles alleging that they are in violation of the misbranding and 'New Drug' provisions of the Federal Food, Drug, and Cosmetic Act, and praying that they be seized and condemned.

"3. On October 20, 1958, pursuant to said Libel and process issued thereunder, the United States Marshal for this District seized said articles in the possession of the Glenway Company, 4427 San Fernando Road, Glendale, California, where they were being held for sale. [Request 19, deemed admitted].

"4. On December 31, 1958, due notice having been given to all persons to appear and present their claims and no person having appeared, a Final Decree by default was entered ordering said articles condemned and destroyed.

"5. On January 21, 1959, a Stipulation and Order was entered vacating said Final Decree and giving Cornell Drug Corporation time until January 23, 1959, to file a Claim, Answer and Cost Bond.

"6. On January 23, 1959, an Answer and Claim was filed on behalf of Cornell Drug Corporation, a New York corporation asserting ownership of the articles under seizure and claiming said articles.

"7. Said Answer and Claim admits the shipment in interstate commerce of the aforesaid articles as alleged in the Libel of Information, and admits that such articles are drugs, but denies the other allegations of the Libel.

"8. On February 20, 1959, libelant filed and served upon the claimant Written Interrogatories Under Rule 33, giving claimant 15 days to respond.

"9. On February 20, 1959, libelant filed and served upon the claimant Requests For Admission Under Rule 36, giving claimant 15 days to respond.

"10. Claimant obtained a number of extensions of time to file answers to the Written Interrogatories and did file Answers to Interrogatories on June 26, 1959.

"11. Claimant at no time obtained an extension of time to respond to the Requests For Admission. On June 26, 1959, claimant filed a document entitled 'Admissions Under Rule 36' purporting to respond to the aforesaid Requests For Admission.

"12. On August 13, 1959, libelant filed a Motion to Strike claimant's 'Admissions Under Rule 36.'

"13. On October 9, 1959, an Order was entered granting libelant's Motion to Strike claimant's 'Admissions Under Rule 36.'

"14. On October 12, 1959, claimant filed a Motion for the nunc pro tune filing of said 'Admissions Under Rule 36,' and alleging excusable neglect on the part of claimant's attorney for the late filing. Said Motion was denied by Order entered on November 13, 1959, and the Requests For Admission are deemed admitted.

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"18. Said retail packages, display cartons, and pamphlets [Exhibits 'A', 'B', and 'C', attached to Requests For Admission] accompanied and related to said Trim Cigarettes, described the purposes and directions for use of such cigarettes, and were designed to induce and stimulate sales of such cigarettes.

"19. Libelant has filed a Motion for Summary Judgment supported by affidavits.

<sup>1</sup> Findings of Fact Nos. 15, 16 and 17 quote the printed matter of the labels on the retail packages and display cartons and of the labeling accompanying the article.

"20. Said Trim Cigarettes are offered to the public and are intended for use as an effective means of dealing with problems of obesity or overweight; they are represented as being capable of curbing the appetite, satiating hunger, and causing loss of weight without pills or diet. [Exhibits 'A', 'B', 'C', 'D', 'E', 'F', 'G', and 'H', attached to Requests For Admission; Requests 13-18 deemed admitted].

"21. Said Trim Cigarettes are intended to affect the structure and functions of the body of man. [Exhibits 'A', 'B', 'C', 'D', 'E', 'F', 'G', and 'H', attached to Requests For Admission].

"22. Said Trim Cigarettes contain combustible tartaric acid. [Exhibit 'A' attached to Requests For Admission; Answers to Interrogatory 9].

"23. Tartaric acid in cigarettes is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use in a recurring condition such as obesity. [Affidavits of Dr. Grollman, Dr. Modell, Dr. Richardson, and Dr. Smith—Exhibits 'A', 'B', 'C', and 'D' appended to libelant's Motion for Summary Judgment].

"24. There is no New Drug Application on file with the Food and Drug Administration of the Department of Health, Education, and Welfare, for 'Trim Reducing-Aid Cigarettes' or for any similar product. [Affidavit of Dr. Smith, Exhibit 'D', appended to libelant's Motion for Summary Judgment].

"25. The pamphlets which accompanied said Trim Cigarettes during their interstate journey and while they were held for sale in Glendale, California, represent and suggest that such cigarettes are absolutely harmless to all users. [Exhibit 'C' (back page) attached to Requests For Admission; Request 14(b) deemed admitted].

"26. Persons who are not permitted to smoke cigarettes for health reasons should not smoke Trim Cigarettes. [Answer to Interrogatory 62(g); see also affidavits of Dr. Grollman, Dr. Modell, Dr. Richardson, and Dr. Smith—Exhibits 'A', 'B', 'C', and 'D' appended to libelant's Motion for Summary Judgment].

"27. The representation and suggestion that Trim Cigarettes are absolutely harmless to all users is false and misleading.

"28. The immediate container of said Trim Cigarettes is the retail package. [Exhibit 'A' attached to Requests For Admission; Request 1, deemed admitted].

"29. The retail package of said Trim Cigarettes bears a label which declares that said product was manufactured for Cornell Drug Corp., but the label does not contain the place of business of the manufacturer, packer, or distributor. [Exhibit 'A' attached to Requests For Admission].

"30. There is no genuine issue as to any of the material facts hereinabove stated.

"Based upon the foregoing Findings of Fact, this Court makes the following Conclusions of Law:

#### CONCLUSIONS OF LAW

"1. The Trim Cigarettes under seizure in this case, together with the retail packages, display cartons, and pamphlets described in the Findings of Fact, were shipped in interstate commerce from New York, New York, to Glendale, California, where they were being held for sale at the time of seizure.

"2. Said articles were seized by the United States Marshal for this District at Glendale, California, within the jurisdiction of this Court, pursuant to 21 U.S.C. 334(a).

"3. Said Trim Cigarettes are drugs within the meaning of 21 U.S.C. 321(g) (3) since they are intended to affect the structure and functions of the body of man.

"4. The written, printed, and graphic matter upon said retail packages constitute the label of said Trim Cigarettes within the meaning of 21 U.S.C. 321(k) since said retail packages are the immediate containers of said cigarettes.

"5. Said retail packages, display cartons, and pamphlets comprise the labeling of said Trim Cigarettes within the meaning of 21 U.S.C. 321(m) since they (1) accompanied and related to said cigarettes when introduced into and while in interstate commerce, and while held for sale after ship-

ment in interstate commerce, (2) described the purposes and directions for use of said cigarettes, and (3) were designed to induce and stimulate sales of such cigarettes. See *United States v. Kordel*, 335 U.S. 345 (1948).

"6. The statute does not exempt from the definition of labeling any written, printed, or graphic matter which accompanies and relates to a drug regardless of whether such matter is distributed only to druggists and not to the public. See 21 U.S.C. 321(m).

"7. Said Trim Cigarettes are new drugs within the meaning of 21 U.S.C. 321(p)(1) in that their composition is such that they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, and suggested in the labeling thereof. See *Merritt Corporation v. Folsom*, 165 F. Supp. 418 (U.S.D.C., D.C. 1958).

"8. Said Trim Cigarettes are new drugs which could not lawfully be introduced into interstate commerce under the provisions of 21 U.S.C. 355, since a New Drug Application with respect to such product had not been filed pursuant to such section and was not effective.

"9. Said Trim Cigarettes are misbranded within the meaning of 21 U.S.C. 352(a) in that their labeling is false and misleading since it represents and suggests that said cigarettes are absolutely harmless to all users whereas such cigarettes are not absolutely harmless to all users.

"10. Said Trim Cigarettes are misbranded within the meaning of 21 U.S.C. 352(b)(1) in that they are drugs in package form and fail to bear a label containing the place of business of the manufacturer, packer, or distributor.

"11. The summary judgment procedure is available in seizure actions brought under the Federal Food, Drug, and Cosmetic Act. *Alberty Food Products Co. v. United States*, 185 F. 2d 321, 326 (9th Cir. 1950).

"12. Said Trim Cigarettes are subject to condemnation under 21 U.S.C. 334(a) and libelant is entitled to a summary judgment ordering such condemnation.

"13. Pursuant to the last sentence of 21 U.S.C. 334(d), said Trim Cigarettes shall be disposed of by destruction.

"14. Claimant shall pay all costs of this proceeding which are taxable against it under 21 U.S.C. 334(e).

"Based upon the foregoing Findings of Fact and Conclusions of Law, the Court hereby renders the following Summary Judgment:

#### SUMMARY JUDGMENT

"The libelant having filed a Motion for Summary Judgment, and the Court having considered the pleadings, admissions, and affidavits on file as well as the briefs and arguments of counsel for libelant and counsel for claimant, and the Court having made Findings of Fact and Conclusions of Law,

"IT IS HEREBY ORDERED, ADJUDGED, and DECREED that the Trim Cigarettes under seizure in this action are drugs within the meaning of 21 U.S.C. 321(g)(3) and are also new drugs within the meaning of 21 U.S.C. 321(p)(1); and it is further

"ORDERED, ADJUDGED, and DECREED that said Trim Cigarettes were misbranded within the meaning of 21 U.S.C. 352(a), when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, in that their labeling is false and misleading since it represents and suggests that said cigarettes are absolutely harmless to all users whereas such cigarettes are not absolutely harmless to all users; and it is further

"ORDERED, ADJUDGED, and DECREED that said Trim Cigarettes were misbranded within the meaning of 21 U.S.C. 352(b)(1), when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, in that they are drugs in package form and fail to bear a label containing the place of business of the manufacturer, packer, or distributors; and it is further

"ORDERED, ADJUDGED, and DECREED that said Trim Cigarettes are new drugs which could not lawfully be introduced into interstate commerce under the provisions of 21 U.S.C. 355 since a New Drug Application with respect to such product had not been filed pursuant to such section

and was not effective at the time said cigarettes were introduced into interstate commerce; and it is further

"ORDERED, ADJUDGED, and DECREED that the articles under seizure be, and they hereby are, condemned pursuant to 21 U.S.C. 334(a); and it is further

"ORDERED, ADJUDGED, and DECREED that the United States Marshal for this District shall destroy all of the articles under seizure in this proceeding, and make his return to the Clerk of this Court; and it is further

"ORDERED, ADJUDGED, and DECREED that the claimant, Cornell Drug Corporation, shall pay all costs of this proceeding which are taxable under 21 U.S.C. 334(e) and under general principles of law, in the sum of \_\_\_\_\_."

**6306. Trim Reducing-Aid cigarettes. (F.D.C. No. 42221. S. No. 15-233 P.)**

**QUANTITY:** 14 shipping cases, each containing 30 bulk ctns., each bulk ctn. containing 10 retail pkgs. of 20 cigarettes each, at Cleveland, Ohio.

**SHIPPED:** 8-22-58 and 9-8-58, by Cornell Drug Corp., New York, N.Y.

**LABEL IN PART:** (Retail pkg.) "Trim Reducing-Aid Cigarettes Filter Tip-20."

**ACCOMPANYING LABELING:** Placards reading in part "Overweight," "No diet No exercise" and "Trim Reducing-Aid Cigarettes \* \* \* Clinically Tested."

**LIBELED:** 10-9-58, N. Dist. Ohio.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained the same false and misleading statements that were in the labeling of the article involved in the case reported above in notice of judgment No. 6304; 502(b)(1)—the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to the drug.

**DISPOSITION:** On 12-12-58, the Cornell Drug Corp., appeared as claimant and filed an answer denying that the article was misbranded, or a new drug. Thereafter, the Government filed written interrogatories which the claimant failed to answer, and on 6-18-59, a default decree was entered providing for condemnation and ordering the destruction of the article. Execution of the decree was stayed pending adjudication of a similar case pending in the District of New Jersey (see notice of judgment No. 6304). Following the entry of a decree of condemnation and destruction in the New Jersey case, the article in this case was destroyed.

**6307. Trim Reducing-Aid cigarettes. (F.D.C. No. 42261. S. No. 22-017 P.)**

**QUANTITY:** 487 bulk ctns., each containing 1 display ctn. containing 10 retail pkgs. of 20 cigarettes each, at Kansas City, Kans.

**SHIPPED:** 7-10-58 and 8-20-58, by Cornell Drug Corp., New York, N.Y.

**LABEL IN PART:** (Retail pkg.) "Trim Reducing-Aid Cigarettes Filter Tip-20."

**LIBELED:** 9-26-58, Dist. Kans.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained the same false and misleading statements that were in the labeling of the article involved in the case reported above in notice of judgment No. 6304; 502(b)(1)—the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to the drug.